General

Guideline Title

Assessment and management of chronic pain.

Bibliographic Source(s)

Hooten WM, Timming R, Belgrade M, Gaul J, Goertz M, Haake B, Myers C, Noonan MP, Owens J, Saeger L, Schweim K, Shteyman G, Walker N. Assessment and management of chronic pain. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2013 Nov. 105 p. [168 references]

Guideline Status

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- December 14, 2016 – General anesthetic and sedation drugs: The U.S. Food and Drug Administration (FDA) is warning that repeated or lengthy use of general anesthetic and sedation drugs during surgeries or procedures in children younger than 3 years or in pregnant women during their third trimester may affect the development of children's brains. Consistent with animal studies, recent human studies suggest that a single, relatively short exposure to general anesthetic and sedation drugs in infants or toddlers is unlikely to have negative effects on behavior or learning. However, further research is needed to fully characterize how early life anesthetic exposure affects children's brain development.
- August 31, 2016 – Opioid pain and cough medicines combined with benzodiazepines: A U.S. Food and Drug Administration (FDA) review has found that the growing combined used of opioid medicines with benzodiazepines or other drugs that depress the central nervous system (CNS) has resulted in serious side effects, including slowed or difficult breathing and deaths. FDA is adding Boxed Warnings to the drug labeling of prescription opioid pain and prescription opioid cough medicines and benzodiazepines.
- March 22, 2016 – Opioid pain medicines: The U.S. Food and Drug Administration (FDA) is warning about several safety issues with the entire class of opioid pain medicines. These safety risks are potentially harmful interactions with numerous other medications, problems with the adrenal glands, and decreased sex hormone levels. They are requiring changes to the labels of all opioid drugs to warn about these risks.

Recommendations

Major Recommendations

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary. The recommendations that follow are based on the previous version of the guideline.

Note from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI): For a description of what has changed since the previous version of this guidance, refer to Summary of Changes Report–November 2013 . In addition, ICSI has made a decision to transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. This document is in transition to the GRADE methodology. Transition steps incorporating GRADE methodology for this document include the following:

- Priority placed upon available systematic reviews in literature searches.
- All new literature considered by the work group for this revision has been assessed using GRADE methodology

The recommendations for the assessment and management of chronic pain are presented in the form of two algorithms with 25 components, accompanied by detailed annotations. Algorithms are provided in the original guideline document at the ICSI Web site for Assessment and Management. Clinical highlights and selected annotations (numbered to correspond with the algorithm) follow.

Class of evidence (Low Quality, Moderate Quality, High Quality, Meta-analysis, Systematic Review, Decision Analysis, Cost-Effectiveness Analysis, Guideline, and Reference) definitions are provided at the end of the "Major Recommendations" field.

Both the Triple Aim and the national *Choosing Wisely® Campaign*, an initiative of the American Board of Internal Medicine (ABIM), offer direction to address human and economic factors in transforming health. The national *Choosing Wisely Campaign's* goal is to help physicians and patients talk about medical tests and procedures that are often used but may not be necessary, and in some cases cause harm. The *Choosing Wisely* logo will appear in the original guideline document whenever a recommendation from a medical specialty society participating in the *Choosing Wisely Campaign* is in alignment with ICSI work group recommendations.

Clinical Highlights

- Chronic pain assessment should include determining the mechanisms of pain through documentation of pain location, intensity, quality and onset/duration; functional ability and goals; and psychological/social factors such as depression or substance abuse. (*Annotations #2, 3, 12; Aim #2*)
- The goal of treatment is an emphasis on improving function through the development of long-term self-management skills including fitness and a healthy lifestyle in the face of pain that may persist. (*Annotation #14, Aim #1*)
- A patient-centered, multifactorial, comprehensive care plan is necessary, one that includes addressing biopsychosocial factors. Addressing spiritual and cultural issues is also important. It is important to have an interdisciplinary team approach coordinated by the primary care physician to lead a team including specialty areas of psychology and physical rehabilitation. (*Annotation #14, Aim #3*)
- Level I treatment approaches should be implemented as first steps toward rehabilitation before Level II treatments are considered. (*Annotation #14; Aim #3*)
- Medications are not the sole focus of treatment in managing pain and should be used when needed to meet overall goals of therapy in conjunction with other treatment modalities. (*Annotations #14, 19; Aims #4, 5*)
- Careful patient selection and close monitoring of all non-malignant pain patients on chronic opioids is necessary to assess the effectiveness and watch for signs of misuse or aberrant behavior. (*Annotation #19; Aim #5*)

Assessment Algorithm Annotations

2. Critical First Step: Assessment
   Recommendations:

   - A clinician should complete an adequate pain assessment on all patients, that includes documentation of pain location, intensity, quality, onset/duration/variations/rhythms, manner of expressing pain, pain relief, exacerbation triggers, effects of pain, and response to previous treatments.
   - A clinician should complete a general history and physical, including psychiatric comorbidities.

   All patients have the right to an adequate pain assessment including documentation of pain location, intensity, quality, onset/duration/variations/rhythms, manner of expressing pain, pain relief, exacerbation triggers, effects of pain, and response to previous treatment. The plan should include pain assessment tools that are appropriate for the individual, with self-report being the primary source, which includes the facilitation of regular reassessment and follow-up according to criteria developed by the individual organization. Some inquiry of sleep and diet is also helpful.

It is also essential to elicit any history of depression or other psychopathology that may affect the perception of pain *[High Quality Evidence]*, *[Low Quality Evidence]*. Past or current physical, sexual, or emotional abuse is also an important factor. A history of chemical dependency is of interest in this patient population. Also see Annotation #12, "Other Assessment," below and in the original guideline document.

Chronic pain frequently involves the musculoskeletal system and the nervous system, especially the spine and its contents. These areas should be examined more carefully and with attention to possible generators of pain relative to the patient's history.

Musculoskeletal: Observe for obvious deformity or atrophy. If atrophy is suspected, it should be measured. Asymmetry of the iliac crests can be a sign of sacroiliac joint pathology. Although scoliosis may be present, it is usually not a cause of pain.

Cyanosis or pallor of an extremity is also useful information as is asymmetry of limb temperature. Examine posture gait and station. Range of motion of the spine does not correlate well with pathology. It has more significance in peripheral joint pathology. Involved joints should be examined for signs of effusion, instability, and ligament or cartilage pathology. Palpation for areas of spasm or tenderness and for identification of trigger points is useful *[Low Quality Evidence]*.

Neurological: Some brief assessment of mental status is appropriate. Patients with significant cognitive or language function impairment will be much more challenging to treat. Much of the identifiable findings in patients with chronic pain will be referable to the peripheral nervous system. Therefore careful evaluation of muscle strength, sensation, and muscle stretch reflexes is important. Findings of allodynia (sensitivity to a non-noxious stimulus like light touch or rubbing) and hyperalgesia are useful in any pain syndrome. Signs and symptoms of upper motor neuron dysfunction will provide clues to the existence of potentially painful conditions such as multiple sclerosis or myelopathy due to cervical spinal stenosis. Patients with hemiplegia or hemiparesis may present with central type pain syndromes.

Diagnostic Testing

There is no diagnostic test for chronic pain. It is important to remember that finding pathology on diagnostic tests does not necessarily prove that the identified pathology is causing the patient's pain. Nevertheless, diagnostic testing is useful in patients with chronic pain for helping to direct treatment and referral.

Plain radiography is helpful in musculoskeletal pain to rule out pathology that might require more immediate attention (e.g., an unrecognized fracture or mass lesion).

Magnetic resonance imaging (MRI) and computed tomography (CT) are used very frequently, especially in spine-related pain. MRI is usually preferred for evaluating disc pathology. Some general information about MRI in the spine and pain is important in interpreting these studies. Bulging discs are usually not significant in the absence of spinal stenosis. Disc degeneration and arthritic changes per se are not necessarily painful. The size of a disc protrusion does not correlate with pain level. Most pain physicians like to have this information when evaluating the patient, especially if some anesthesiologic intervention is contemplated for the pain. CT and CT myelography are useful in patients who cannot undergo MRI or who are being considered for surgery. Electromyography and nerve conduction studies are of use in patients suspected of having lower motor neuron dysfunction, nerve or nerve root pathology, or myopathy *[Low Quality Evidence]*, *[Guideline]*.

Functional/Quality-of-Life Assessment Tools

Many patients with chronic pain have significant losses in ability to perform normal life activities. Baseline functional ability assessment can provide objectively verifiable information about a patient's quality of life and ability to participate in normal life activities. These tools often also include measures of pain perception, psychological status, as well as function.

- Palliative Performance Scale (Karnofsky Scale) (see the NGC summary of the ICSI guideline Palliative care for adults.)
- Oswestry Low Back Disability Index (see the NGC summary of the ICSI guideline Adult acute and subacute low back pain.)
- 36-item Short Form Health Survey (SF-36)
- U.S. Department of Labor Physical Demand Table
- American Pain Foundation Scale (adapted from Oken, M.M.)
- EuroQual questionnaire (EQ5D-5L)

This information may then be used for:

- Identifying significant areas of impairment or disability
- Establishing specific functional outcome goals within a care plan
- Measuring the effectiveness of the care plan or treatment interventions

See also Appendix C in the original guideline document for the Physical Functional Ability Questionnaire (FAQ5).

Pain Assessment Tools

Patient self-report is the "most reliable indicator of the existence and intensity of pain" (National Institutes of Health) and is a key component of chronic pain assessment. Tools to assess chronic pain should:

- Be appropriate to the person regardless of age, race, creed, socioeconomic status and psychological or emotional background
- Include a multidimensional scale since chronic pain affects a person's entire being *[Low Quality Evidence]*
- Address location, quality, sensory characteristics, intensity, duration, aggravating and alleviating factors, variability, and predictability
- Be used early in the process of patient evaluation

Refer to the original guideline document for more information on the following topics: multidimensional assessment tools, single-dimensional assessment tools, patients with barriers to communications that can affect assessment, and a general approach to use of pain assessment tools in chronic pain.

3. Determine Biological Mechanisms of Pain
   There are many ways to classify types of pain. Based on consensus, the work group found it most helpful to classify this guideline by the following four types: neuropathic, inflammatory, muscle, and mechanical/compressive.

   It is important to determine which of these mechanisms are at work in the chronic pain patient because the treatments depend on the type of pain. A few decades ago, the type of pain was not so important because all pain was treated in a similar way with a very narrow scope of drugs and therapies – basically non-steroidal anti-inflammatory drugs (NSAIDs), acetaminophen, and sometimes opioids. There are now available mechanism-specific treatments for neuropathic pain, inflammatory pain, bone pain, and muscle dysfunction.

   Remember that patients often will present with pain that has more than one mechanism. The clinician should determine the relative contribution of each mechanism to the total pain condition and devise treatment strategies to address the relevant mechanisms. If there is diagnostic uncertainty, the clinician may refer to or consult a pain specialist *[Low Quality Evidence]*.

4. Neuropathic Pain
   Neuropathic pain is pain produced by damage to or dysfunction of the somatosensory system. Examples include sciatica from nerve root compression, diabetic peripheral neuropathy, trigeminal neuralgia, and postherpetic neuralgia. The features that indicate neuropathic pain are: the clinical setting, the distribution, the character of the pain and the physical examination findings. The clinical setting is usually the first clue to neuropathic pain. A diabetic who complains of persistent pain is likely to have neuropathic pain since about 50% of diabetics develop neuropathy-related pain. A patient who develops pain after a stroke in the same location is most likely having post-stroke neuropathic pain. The character of neuropathic pain is usually described as burning or shooting/stabbing. If the pain follows a nerve distribution (e.g., median nerve for carpal tunnel syndrome), neuropathic pain should be considered. Other examples are stocking-glove distribution for peripheral neuropathy, trigeminal distribution for trigeminal neuralgia, and dermatomal distribution for postherpetic neuralgia. The physical findings to look for with neuropathic pain are numbness in the pain territory, sensitivity to a non-noxious stimulus like light touch or rubbing *(allodynia)*, or coolness of the skin in the pain territory (sympathetically mediated pain).

   Fibromyalgia syndrome is characterized by widespread musculoskeletal aching, stiffness, and tenderness. Accumulating research suggest fibromyalgia is a centrally mediated neuropathic pain syndrome and may be considered a special case within neuropathic pain. It is one of the most common pain clinic diagnoses.

   The 2010 American College of Rheumatology Diagnostic Criteria for Fibromyalgia:

   - Presentation of widespread pain and symptoms for three months or more
   - Widespread pain index that assesses the number of painful body areas (healthcare professional [HCP]-administered questionnaire)
   - Symptom Severity Scale that assesses the severity of fatigue, waking unrefreshed and cognitive symptoms, as well as the extent of other somatic symptoms (HCP-administered questionnaire)

   Additional information regarding the American College of Rheumatology Diagnostic Criteria for Fibromyalgia can be found at http://www.fibroknowledge.com/site/acr-2010.htm.

   [Low Quality Evidence]

5. Muscle Pain
   Skeletal muscle pain is a common cause of chronic pain. Failure to properly diagnose muscle pain may result in poor treatment outcome, delayed recovery, and ineffective, unnecessary surgery.

   Myofascial pain is regional muscle soft tissue pain commonly involving the neck, shoulders, trunk, arms, low back, hips, and lower

extremities. It is characterized by painful muscle dysfunction in one or several muscles in a region of the body with loss of range of motion; and by tenderness at muscle sites that causes a referred pain in a typical distribution (trigger points). Commonly, taut bands of muscle are present and sometimes a muscle twitch is elicited with palpation or needling the affected muscle. Myofascial pain is common in patients seen in pain clinics. It usually presents after an injury or with occupational repetitive activity. Treatment consists more in restoring muscle balance and function through physical therapy techniques than with medication management. Identifying and managing perpetuating factors (posture, repetitive actions, occupational factors) is a priority in treatment. Trigger point injections or acupuncture can be useful adjunctive treatment that may hasten recovery. Consider myofascial pain when there is regional pain without any findings on imaging studies. Sometimes, persistent myofascial pain may be a muscle response to an underlying structural spine or visceral problem *[Low Quality Evidence]*.

6. Inflammatory Pain
   The inflammatory component of pain as seen in arthritis, infection, tissue injury, and postoperative pain is also known as *nociceptive pain* because the inflammatory mediators activate primary sensory nerves that carry pain information to the spinal cord. The clinical features include heat, redness, and swelling at the pain site and a history of injury or known inflammation. Treatment involves managing the inflammatory process with antibiotic or immune modulating agents and using anti-inflammatory agents like NSAIDs or corticosteroids to manage symptoms and control inflammation.

7. Mechanical/Compressive Pain
   Mechanical pain is aggravated by activity and temporarily relieved by rest. Neck and back pain are commonly related to muscle/ligament strain sprain, degeneration of disks or facets, or osteoporosis with compression fractures *[Low Quality Evidence]*.

   Mechanical/compressive pain is also a type of nociceptive pain because mechanical pressure or stretching directly stimulates the pain sensitive neurons. In this setting, the history and radiological findings usually tell the story. Examples include fracture, obstruction, dislocation, or compression of tissue by tumor, cyst, or bony structure. The treatment may require some sort of decompression or stabilization. See also the NGC summary of the ICSI guideline Adult acute and subacute low back pain.

8. Is Pain Chronic?
   There is variation regarding the definition of chronic pain, including:

   - Persistent pain, which can be either continuous or recurrent and of sufficient duration and intensity to adversely affect a patient's well-being, level of function, and quality of life *[Low Quality Evidence]*.
   - Pain without apparent biological value that has persisted beyond the normal tissue healing time (usually taken to be three months), per the International Association for the Study of Pain.
   - The work group has defined chronic pain as "pain without biological value that has persisted beyond the normal time and despite the usual customary efforts to diagnose and treat the original condition and injury."

   If the patient has not been previously evaluated, attempt to differentiate between untreated acute pain and ongoing chronic pain. If a patient's pain has persisted for six weeks (or longer than the anticipated healing time), a thorough evaluation for the cause of the pain is warranted.

11. Specialty Involvement Where Indicated
    Possible correctable causes of pain should be evaluated by the appropriate medical/surgical consultant for evaluation and, if indicated, appropriate correctable treatment.

    Involvement of a pain specialist in the care of a patient with chronic pain occurs optimally when the specialist assumes a role of consultation. The work group noted that board certification as a pain specialist is available through the American Board of Anesthesiology, the American Board of Physical Medicine and Rehabilitation and the American Board of Psychiatry and Neurology. However, there is extensive variability in the needs of patients with chronic pain, and the work group did not want to limit those who could provide care. It is recommended that the primary care clinician receive regular communications from the pain specialist and continue visits with the patient on a regular schedule, even if the patient is involved in a comprehensive management program at a center for chronic pain. The primary care clinician should not expect that a consulting pain specialist will assume primary care of a patient unless there has been an explicit conversation in that regard between the consultant and the primary care clinician. This is particularly true in regard to the prescribing of opioids: the primary care clinician should expect to continue as the prescribing clinician, and ensure the responsible use of the opioids through contracts, urine toxicology screens, etc. (the exception to this may occur with the admission of the patient into an opioid tracking program). Conversely, the consulting pain specialist should not initiate opioids without the knowledge and consent of the primary care clinician.

    Because it is difficult to truly assess a patient's past opioid prescription history, consider consistently querying the Minnesota Prescription Monitoring Program (PMP). Current use of the PMP is growing and can offer a clinician an opportunity to identify concerns about prescription opioids if the patient is a poor historian or is not forthcoming. Non-prescribers can query the PMP as a physician proxy in

order to expedite the process.

Additional information on the Minnesota Prescription Monitoring Program (PMP) can be found at http://pmp.pharmacy.state.mn.us/ .

12. Other Assessment
Recommendations:

- Assessment tools may be utilized to measure, estimate or describe aspects of a patient's level of function, psychological status or quality of life.
- Clinicians should identify and manage comorbid psychological disorders.

Functional/Quality-of-Life Assessment Tools

Patients who experience a loss of ability to perform normal life activities as a result of chronic pain may benefit from having a recurring assessment on a consistent basis for baseline comparison as a patient's treatment progresses. This may allow for continual assessment of the effectiveness of the care plan or treatment interventions.

- Palliative Performance Scale (Karnofsky Scale) (see the NGC summary of the ICSI guideline Palliative care for adults)
- Oswestry Low Back Disability Index (see the NGC summary of the ICSI guideline Adult acute and subacute low back pain)
- SF-36
- U.S. Department of Labor Physical Demand Table
- American Pain Foundation Scale (adapted from Oken, M.M.)
- EQ5D-5L

These tools all have limitations, including difficulties with administration and scoring, disease- or condition-specific design or failure to provide clinically useful information, which have probably contributed to a lack of widespread clinical use.

See also Appendix C in the original guideline document for The Physical Functional Ability Questionnaire (FAQ5).

Psychological Assessment

Determine possible psychiatric contribution to clinical presentation.

Assessment questions to ask the patient:

- Are you depressed or anxious?
- Are you under any psychiatric care?
- Do you have a history of substance abuse?
- Do you have a history of verbal, physical, or sexual abuse?

Refer to the original guideline document for additional information on the following topics:

- Role of psychological assessment including depression, anxiety, substance abuse and dependence, CAGE questionnaire, sleep disorders, personality disorders, and history of abuse
- Coping patterns and resources
- Spirituality
- Work and disability issues
- Contributing factors and barriers to treatment

Management Algorithm Annotations

14. Level I Core Principles
Recommendations:

- The work group recommends a written plan of care using the biopsychosocial model for ensuring a comprehensive approach to treatment of a patient with chronic pain.
- All patients with chronic pain should participate in an exercise fitness program to improve function and fitness (Malmivaara et al., 2006) *[Systematic Review]*.
- Clinicians may consider a cognitive behavioral approach with functional restoration to improve function and help reduce pain. The members of the interdisciplinary team will vary depending on the resources in the community.
- The presence of psychological difficulties should in no way invalidate a patient's complaint of pain, nor should it eliminate the

possibility that a general medical condition may also be present that is causing the pain.
- Shared decision-making for treatment of chronic pain needs an understanding of the patient's ethnic and cultural background, age, gender and spirituality in order to work with the patient's chronic pain symptomatology.
- A clinician should choose positive language and imagery.
- Self-management insures active patient participation in the care plan and is essential.

Plan of Care Using Biopsychosocial Model

The collaborative care model is an approach to health care delivery that includes providing care management and system support *[High Quality Evidence]*. It utilizes a team approach including the patient as a team member and specialty consultation support. Elements of this model include dedicated staff to coordinate, support and educate patients; methods for reliable and systematic patient follow-up; and consistent use of evidence-based treatment practices.

A written plan of care is the essential tool for ensuring a comprehensive approach to treatment of a patient with chronic pain. To maximize the success of treatment, a care plan must address the whole person in all of his/her complexity, including physical and biologic factors, psychological state and beliefs, as well as the family, social, and work environment (biopsychosocial model). It is important to have an interdisciplinary team approach coordinated by the primary care physician to lead a team including specialty areas of psychology and physical rehabilitation.

A plan of care for all patients with chronic pain should address all of the following five major elements:

- Set personal goals
- Improve sleep
- Increase physical activity
- Manage stress
- Decrease pain

Specific and measurable goals and clearly described specific treatment elements give patients a framework for restructuring a life that has often been significantly altered by chronic pain. Failure to improve pain and function when a patient is following the plan of care should lead to changes of the plan. Failure to follow a plan of care should lead to addressing barriers and further evaluation of stressors, psychosocial factors, or motivations.

See Appendix D, "Personal Care Plan for Chronic Pain," in the original guideline document for an example care plan.

Patient Focus Group Feedback

In 2005, ICSI conducted a focus group of patients who had received care for chronic pain. The information gained from these discussions was summarized and presented to the work group as part of the guideline development process. Findings were later shared with ICSI member organizations when the guideline became available for use.

Objectives for conducting the focus group were:

- Learn the patient's perspective on living with chronic pain
- Hear what patients do to manage their pain
- Hear the patient's understanding of available options for treating pain
- Determine how chronic pain influences changes in lifestyle and function
- Understand the patient's perspective of the clinician's role

Key points from the patient focus group discussion include:

- Patient experience is that limited education is done early on and patients do a lot of research on their own. Education is critical and includes setting realistic goals, providing education to patients about their disease state, explaining medications and also any interventional procedures. Well-informed patients will be able to take more responsibility for their care.
- Be aware that the term chronic pain may elicit a highly emotional response. Patients may feel discouraged that the pain will never go away despite their hope a cure will be found.
- Although patients would like a quick fix to their pain, frustration occurs when interventions that only provide temporary relief are found or utilized.
- Patients want to be included in the treatment plan. They are often proactive in seeking ways to alleviate or eliminate their pain. They may see several types of physicians and may have also tried to find relief from their pain in additional varieties of ways. Teamwork and empathetic listening in the development of a treatment plan are critical.
- When the physician acknowledges that chronic pain affects the whole person and really listens, patients are more likely to be open to

learning how to live by managing their pain versus curing their pain.

- Most patients want to return to a normal routine of completing activities of daily living, (e.g., playing with children/grandchildren, going for a walk, and working within their limitations). The focus should be on improving function.
- Many patients have utilized a variety of interventions including medications and complementary therapies.

Level I versus Level II Management

The treatment approaches described in this algorithm for the management of chronic pain are divided into two levels. Level I treatment encompasses the standard approaches to the treatment of chronic pain including pharmacologic management, intervention management, non-pharmacologic management, and complementary medicine management. These treatment approaches should be implemented as first steps towards rehabilitation before Level II treatments are considered. Level II treatment includes referral for interdisciplinary pain rehabilitation or surgery for placement of a spinal cord stimulator or intrathecal pump. Level II treatments may be effective interventions for patients with chronic pain who have failed more conservative treatment options. Level II treatments are designed for the most complex and challenging patients with chronic pain. The treatment options included in Level II are expensive and require a significant investment on the part of the patient to be effective with either level of management. This should ideally be coordinated by the primary care clinician.

Physical Rehabilitation with Functional Goals

Exercise therapy is commonly recommended and used in managing patients with chronic pain. In one study, sixty-one randomized controlled trials involving 6,390 participants were assessed. The authors concluded that exercise therapy is effective in reducing pain and functional limitations in the treatment of chronic low back pain. There were limitations in the quality of the studies, and improvements were small but significant over other conservative treatment options. There was also some evidence of the effectiveness of a graded exercise program in subacute low back pain primarily in reducing work absenteeism *[Meta-analysis]*.

Clinical guidelines for managing patients with low back pain are available from at least 11 countries. Four countries included advice for chronic pain, and all guidelines recommend exercise therapy as useful *[Guideline]*, *[Systematic Review]*. The American Pain Society published an evidence-based clinical practice guideline recommending consideration of an intensive interdisciplinary rehabilitation program for patients with non-radicular low back pain who did not improve with the usual conservative program *[Guideline]*.

No one type of exercise has shown to be more effective than another. Studies have shown benefit of flexion exercises, extension exercises (Mckenzie), isokinetic intensive machine muscle strengthening, and group aerobic low-impact exercises. There is a strong need for high-quality studies to determine which type, and how much, of an exercise is necessary and effective. Cost effectiveness needs to be considered *[Low Quality Evidence]*.

Most patients with chronic pain are physically deconditioned from inactivity. The International Paris Task Force on Back Pain has recommended activity, both recreational as well as formal exercise, for patients with chronic low back pain *[Low Quality Evidence]*.

For patients with subacute low back pain, a graded, gradually progressive, exercise program has been shown to be effective in reducing work absenteeism *[Moderate Quality Evidence]*. Doing a baseline of the patient's present capacity to do exercise, and then using a graded, gradually progressive, program to improve fitness makes sense for all patients with pain.

Geriatric patients also can benefit from a physical rehabilitation program. The American Geriatric Society Panel of Exercise and Osteoarthritis encourages light to moderate intensity physical activity for both prevention and possibly restoration of health and functional capacity in patients with chronic disease *[Meta-analysis]*.

Passive modalities (transcutaneous electrical nerve stimulation [TENS], ultrasound, corset, traction) have limited evidence of effectiveness and should be used only with an active exercise program *[Systematic Review]*. Patient should be taught self-management techniques to help manage their pain including use of ice, heat and massage relaxation *[Low Quality Evidence]*.

Randomized controlled trials support massage therapy for certain types of pain. Reduced pain scores were found for patients receiving massage who had low back pain *[Moderate Quality Evidence]*, *[High Quality Evidence]*, osteoarthritis of the knee *[Moderate Quality Evidence]*, juvenile rheumatoid arthritis *[Moderate Quality Evidence]* and fibromyalgia *[Moderate Quality Evidence]*. It remains to be determined what is the optimal amount of sessions and duration.

Regular physical activity and exercise are important parts of a healthy lifestyle. In addition to playing a role in reducing pain and improving function in patients with chronic pain, physical fitness benefits people with arthritis, heart disease and diabetes. It helps with managing high blood pressure, balance problems and difficulty walking. A recent prospective cohort study, involving 416,175 individuals followed for an average of eight years, proposed that 15 minutes a day of moderate intensity exercise might be of benefit in improving quality of life and longer life expectancy *[Moderate Quality Evidence]*.

Refer to the original guideline document for more information on participation in physical rehabilitation.

Psychosocial Management with Functional Goals

Chronic pain is frequently associated with psychological problems and even comorbid psychiatric diagnoses. The presence of psychological difficulties should in no way invalidate a patient's complaint of pain, nor should it eliminate the possibility that a general medical condition may also be present that is causing the pain. If psychological difficulties or psychiatric comorbidities are found, the patient's treatment plan should include specific steps to address them.

Depression

A high percentage of patients with chronic pain have co-existing depression. In 2004, data were examined from primary care centers world-wide by the World Health Organization. They found that 22% of all primary care patients suffer from chronic debilitating pain. Further, they found that patients with chronic pain were four times more likely to have comorbid depressive disorder than pain-free primary care patients *[Low Quality Evidence]*. The findings also showed that the more diffuse the pain complaints, the greater the risk of depression and the bigger the impact on quality of life.

If depression in a chronic pain patient is severe or comorbid major depressive disorder is present in a patient with chronic pain (see the NGC summary of the ICSI guideline Adult depression in primary care), it is important to note that such patients are at increased risk of suicide *[Low Quality Evidence]*. Specifically assess if patient has considered harming him/herself or made plans to kill him/herself. If suicidal thoughts are present, assess whether patient has a concrete plan for self-harm; assess if they have the means to carry out the plan; and assess lethality of the plan. Suicidal risk is higher in individuals who are struggling with substance use/abuse, because judgment can be impaired. Past suicide attempt(s) increase risk of future attempts.

See also Annotation #12, "Other Assessment," above and in the original guideline document and Annotation #19, "Level I Other Management," below for more information on substance use/abuse.

If suicidality and/or major depressive disorder is present in the context of chronic pain, get psychiatric consultation immediately, because of risk of suicide. Also, management of chronic pain and work towards rehabilitation goals are not possible when severe depression is present. If comorbid major depressive disorder is diagnosed concurrently with chronic pain, depressive symptoms should be the primary focus of treatment. In those patients with either pain or depressive symptoms, assess both domains. Depression may be more than a facet of chronic pain when significant depression symptoms are present. If comorbidity is found between chronic pain and mild to moderate major depression, treat both conditions for optimal outcomes *[Systematic Review]*. If comorbid severe major depressive disorder is diagnosed concurrently with chronic pain, depressive symptoms should be the primary focus of treatment.

Some symptoms of depression including feelings of helplessness, dysphoria, and frustration are generally expected in patients suffering from chronic pain given the impact pain often has on ability to function and enjoy life. If targeted intervention can improve level of physical functioning and quality of life, mild depressive symptoms will likely improve without specific intervention.

Cognitive-Behavior Therapy

Cognitive-behavioral approaches to the rehabilitation of patients with persistent and unremitting chronic pain are considered to be among the most helpful available. Patients may be referred to a cognitive-behavioral therapist, counselor, social worker, or psychologist for treatment. However, there are initial cognitive-behavioral steps that can be implemented by primary care physicians within the busy structure of their practice to assist their patients towards rehabilitation *[Guideline]*. Depending on resources, components of this may be organized in a community setting.

Patients live in environments that exert powerful reinforcement for certain behaviors. Physicians, by their very role as health care clinicians, are powerful reinforcers of behavior. By changing the contingencies of reinforcement, patients can make gains towards significant rehabilitation goals with the help of their physicians. The goals of cognitive-behavioral strategies in the management of chronic pain are to improve physical functioning, assist patients in returning to work, reduce disability, reduce pain-related fear/avoidance, and reduce psychological distress and depression *[Low Quality Evidence]*.

Cognitive-Behavioral Strategies for Primary Care Physicians

There are a number of cognitive-behavioral strategies that primary care providers can utilize to help their patients manage chronic pain.

- Tell the patient that chronic pain is a complicated problem and for successful rehabilitation, a team of health care providers is needed. Chronic pain can affect sleep, mood, levels of strength and fitness, ability to work, family members, and many other aspects of a

person's life. Treatment often includes components of stress management, physical exercise, relaxation therapy and more to help them regain function and improve the quality of their lives.

- Let the patient know you believe that the pain is real and is not in his/her head. Let the patient know that the focus of your work together will be the management of his/her pain. ICSI Patient Focus Group feedback included patient concerns that their provider did not believe them/their child when they reported pain.
- Ask the patient to take an active role in the management of his/her pain. Research shows that patients who take an active role in their treatment experience less pain-related disability *[Low Quality Evidence]*.
- Avoid telling patients to "let pain be their guide," whether it is stopping activity because of pain or taking medications or rest in response to pain.
- Prescribe time-contingent pain medications, not pain medications "as needed." Time-contingent medications allow a disruption in the associations between pain behavior and pain medication. The powerfully reinforcing properties of pain medicines are then not contingent upon high levels of pain and pain behavior.
- Schedule return visits on a regular schedule and don't let the appointments be driven by increasing levels of pain. Physicians are powerful reinforcers, too.
- Reinforce wellness behaviors such as increased activity or participation in an exercise program.
- Enlist the family and other supports to reinforce gains made towards improved functioning, too.
- Have the patient get involved in an exercise program or structured physical therapy.
- Assist the patient in returning to work. Do this in a step-wise fashion that is not dependent on level of pain.
- Fear of movement or fear of pain due to movement is a significant concern for many patients with chronic pain. Inactivity or avoidance of movement leads to physical deconditioning and disability. Try not to rely on sedative or hypnotic medications to treat the fear many chronic patients show of activity or of increased pain. When patients with chronic pain expose themselves to the activities that they fear, which simply means when they do the things they have been afraid of and avoiding, significant reductions are observed in fear, anxiety, and even pain level. If patient's fears are excessive, relaxation strategies may be helpful or referral for more formal and intensive cognitive-behavioral therapy may be necessary.

Refer to the original guideline document for information on the following topics:

- Cognitive-behavioral interventions including relaxation therapies and cognitive techniques
- Culture and chronic pain
- Age and chronic pain
- Gender and chronic pain
- Spirituality and chronic pain

15. Level I Management: Neuropathic Pain

    The first principle guiding any therapy is to eliminate the underlying causes of pain to the greatest possible extent with disease-specific measures *[Guideline]*. For example, better diabetes management should minimize the complications of diabetes, including pain. Chemotherapy or surgery that reduces tumor bulk will decrease pain caused by a tumor that is compressing nerve roots.

    Symptomatic pain control can take the form of local or regional interventions, including nerve blocks, topical agents, or physical rehabilitative measures. In addition, systemic therapies can be applied, such as drug therapies or behavioral techniques that reduce pain *[High Quality Evidence]*.

    Fibromyalgia may be considered a special case within neuropathic pain due to mechanisms that are less well defined and a distribution that is widespread. Treatments proven effective include aerobic exercise, behavioral therapies such as relaxation, interdisciplinary management and acupuncture *[Systematic Review]*, *[High Quality Evidence]*. Pharmacological therapy with U.S. Food and Drug Administration (FDA) indication for fibromyalgia includes pregabalin, duloxetine, and milnacipran. Other agents that have been shown to be effective in controlled trials include gabapentin, cyclobenzaprine, tramadol, and tricyclic antidepressants (TCAs) *[Low Quality Evidence]*.

    Pharmacotherapy

    - TCAs (amitriptyline) have been shown to have a modest benefit in patients with fibromyalgia in reducing pain short-term and reducing insomnia.
    - Cyclobenzaprine also has modest benefit in patients with fibromyalgia and is used as a standard therapy for muscle pain.

    See Appendix H, "Neuropathic Pain Treatment Diagram," in the original guideline document.

    Local or Regional Therapies

    Topical therapies can be applied to localized peripheral tissues to reduce pain without significant systemic effects. Topical capsaicin applied

three or four times per day can deactivate local C-polymodal nociceptors at the vanilloid receptor and reduce pathological pain. It has been studied in diabetic neuropathy *[High Quality Evidence]* and postherpetic neuralgia *[Low Quality Evidence]*. Preparations of topical lidocaine in the form of a cream or a patch have also been used for relief of localized neuropathic pain syndromes *[Moderate Quality Evidence]*. Transcutaneous electrical nerve stimulation and other stimulation-based therapies can provide temporary relief in some cases of neuropathic pain caused by nerve root or plexus lesions, but such therapies may also be irritating, particularly when allodynia is present. In such cases, application of the stimulating electrode in adjacent, uninvolved dermatomes may be effective and better tolerated.

Drug Therapies for Neuropathic Pain

See also Annotation #19, "Level I Other Management," below.

Gabapentin and Pregabalin

Among the many drugs used to manage neuropathic pain, gabapentin and pregabalin have growing acceptance among pain specialists and neurologists as a first-choice treatments. Gabapentin provides a high level of pain relief in up to one-third of the people who take it for neuropathic pain, and both gabapentin and pregabalin have proved effective in postherpetic neuralgia and diabetic neuropathy in multicenter controlled trials *[Systematic Review]*, *[Moderate Quality Evidence]*, *[High Quality Evidence]*. Their favorable side effect profile and paucity of adverse interactions with other drugs contribute to their widespread use in neuropathic pain. Since excretion of the drug is virtually 100% renal, the dose and frequency of administration is reduced in patients with renal insufficiency. Pregabalin, like gabapentin, modulates the alpha2delta subunit of the N-type voltage-gated calcium channels, and thus regulates the influx of calcium into the nerve and reduces the outflow of excitatory neurotransmitters that transmit pain. Pregabalin is indicated for treatment of diabetic neuropathy, postherpetic neuralgia and fibromyalgia, as well as for partial onset seizures. Gabapentin has an indication for diabetic neuropathy pain, postherpetic neuralgia, fibromyalgia, and partial onset seizures. Several studies have also shown that pregabalin for neuropathic pain associated with spinal cord injuries was efficacious and that the risk for adverse events was comparable to other pharmacologic therapies *[Systematic Review]*.

Other Anticonvulsants

Other anticonvulsants have been utilized in neuropathic pain with variable success. Carbamazepine is still considered a good initial choice for idiopathic trigeminal neuralgia, but there is a lack of evidence of consistent success in other pain states. Oxcarbazepine is chemically similar to carbamazepine and may have benefits in the treatment of neuropathic pain, including trigeminal neuralgia.

Newer anticonvulsants are beginning to be investigated for their neuromodulating effects on various non-epileptic conditions such as mood, behavior, and pain. Among these drugs are topiramate, lamotrigine, oxcarbazepine, and tiagabine. Some preliminary studies have indicated a possible role for lamotrigine in trigeminal neuralgia *[Low Quality Evidence]*, painful human immunodeficiency virus (HIV)-associated neuropathy *[Low Quality Evidence]*, and complex regional pain syndrome type I *[Low Quality Evidence]*.

TCAs

TCAs (amitriptyline, nortriptyline, desipramine, imipramine, and others) continue to hold a place in the management of a broad range of pain disorders, including neuropathic pain. Their mechanism of action is believed to involve potentiation of descending inhibitory pathways, especially at the level of the lower brainstem. Among the large number of controlled and uncontrolled studies, superior efficacy for amitriptyline or desipramine over fluoxetine or lorazepam was demonstrated in diabetic neuropathy *[Low Quality Evidence]*. This trial showed that the effect of the TCA on pain was independent of its effect on depression. A screening electrocardiogram is recommended for elderly patients and others at risk of the conduction delay that these drugs can cause. Duloxetine and venlafaxine also have been shown to be effective in certain neuropathic states such as painful diabetic neuropathy and fibromyalgia *[High Quality Evidence]*, *[Low Quality Evidence]*. For more information see Annotation #19, "Level I Other Management: Pharmacologic Management" section, below.

Opioids

Although most opioids are not known to work through antineuropathic mechanisms, they are nevertheless potent analgesics. They have a role in reliable patients when other measures fail. Careful patient selection is critical to success with long-term opioid therapy. Two opioids, methadone and tramadol, may be more effective than others in neuropathic pain. Tramadol is a weak opioid analgesic that also causes serotonin reuptake inhibition similar to that seen with the TCAs. This dual mechanism may make it advantageous for management of neuropathic pain or mixed pain disorders. Tapentadol, a new opioid analgesic with norepinephrine reuptake inhibition properties is available in both immediate-release (IR) and extended-release (ER) oral dosage forms. It is indicated for treatment of neuropathic pain including diabetic peripheral neuropathy. Tapentadol should be avoided in patients with convulsive disorders and in those with severe renal or hepatic impairment.

Refer to the original guideline document for more information.

16. Level I Management: Muscle Pain
    - Currently, scientific evidence of the effectiveness of treatment for muscle pain, such as diffuse nonspecific myalgias, is lacking. In the absence of evidence, the following assessments and treatment will support patient care.
    - Screen for serious medical pathology, for psychological and social factors that may delay recovery.
    - Use a numeric pain rating and functional scale to determine severity of pain disability.
    - A graded exercise program starting within baseline and gradually increasing in a time-contingent manner works best.
    - Use the biopsychosocial interdisciplinary team approach with cognitive-behavioral component encouraging exercise and active participation of the patient in the plan of care *[Low Quality Evidence]*:
      Physical Rehabilitation
        - Fitness program
            - Gentle graded strength
            - Cardiovascular
            - Flexibility
            - Balance
        - Body mechanics
        - Modalities
            - Ice/heat
            - Massage
            - Self-management
        - Aquatic therapy

      Behavioral Management
        - Depression/stress
        - Relaxation techniques
        - Cognitive behavioral
        - Chemical dependency
        - Anger management
        - Biofeedback

      Drug Therapy
        - Pain and sleep
            - TCAs (nortriptyline low dose)
            - Cyclobenzaprine
        - Depression and pain
        - Opioids rarely needed
          [Low Quality Evidence]

    Additional Considerations

    For patients with fibromyalgia chronic pain, physical rehabilitation is the mainstay of management.

    Determine the patient's baseline fitness, and then use a graded exercise program.

    Psychosocial rehabilitation including cognitive behavioral therapy (management of depression, stress, anger, fear avoidance, chemical dependency and non-restorative sleep) is helpful. A biopsychosocial interdisciplinary team approach is most effective.

    Invasive procedures lack evidence of efficacy.

    Self-management insures active patient participation in managing pain and achieving reasonable functional goals.

    Teach self-management and measure outcome using pain rating and a function tool.

17. Level I Management: Inflammatory Pain
    Arthritis, tendinitis and chronic infections are common examples of chronic inflammatory pain. They are associated with swelling and warmth of tissue and sometimes redness of the skin. This type of pain occurs through activation of nociceptors by inflammatory mediators like prostaglandins and can also become chronic through a process of sensitization. Treatment should start with efforts to control the inflammation and its causes when possible. NSAIDs, corticosteroids are the main anti-inflammatory agents. Consider a rheumatology

consult if clinically indicated.

18. Level I Management: Mechanical/Compressive Pain
Mechanical/compressive pain refers to tumors or cysts that may compress pain sensitive structures. Dislocations, instabilities, fractures, etc., may also cause a strain on pain sensitive structures. These causes of persistent pain may be effectively treated with surgical decompression or stabilization, splinting, strengthening and use of assistive devices. Medications play a less prominent role and tend to be less effective when dealing with mechanical or compressive causes of persistent pain. Opioids may be used to manage the symptoms while other measures are being taken.

    Manipulative Therapy and Chronic Pain

    A growing body of evidence supports the integration of manipulative therapy, within the context of interdisciplinary treatment, to be an efficient and efficacious treatment in improving pain and function. As such, manual therapy and treatment should be considered as a viable option in the management of chronic pain, especially when integrated with other interdisciplinary treatments. *[Low Quality Evidence]*, *[High Quality Evidence]*.

19. Level I Other Management
Pharmacologic Management

    Recommendations:

    - NSAIDs should be used for periodic flare-ups of mild to moderate inflammatory or non-neuropathic pain.
    - Clinicians should define the goals of therapy before prescribing medications, and tailor medications to meet the individual goals of each patient.
    - Clinicians should identify and treat specific source(s) of pain.
    - Clinicians should educate patients about the risks and benefits of all drugs, and watch for and manage side effects.
    - For opioid therapy clinicians should:
        - Assure the benefit clearly outweighs the risk when prescribing opioids.
        - Use caution before starting a patient on long-term opioid therapy.
        - Follow the 4 A's (Analgesia, Adverse drug reactions, Activity, Adherence) (Passik & Weinreb, 2000) *[Guideline]*.
        - The work group recommends the use of a written opioid agreement for patients anticipated to be on long-term therapy. See Appendix F in the original guideline document for an example of an opioid agreement form.

    Medications are not the sole focus of treatment in managing pain. They should be used when needed to meet overall goals of therapy in conjunction with other treatment modalities: psychosocial and spiritual management, rehab and functional management, non-pharmacologic and complementary medicine, and intervention management. Pharmacotherapy may include agents to treat specific types of pain, such as neuropathic pain, or adjunctive therapies to treat other comorbidities such as depression and anxiety. Use of medications therefore should be directed not just towards pain relief, but increasing function and restoring overall quality of life.

    The off-label use of medications to treat chronic pain is a common practice, and due to the complexity of chronic pain and the minimal approval sought by drug manufacturers, many of the medications in this guideline have not undergone formal evaluation by the FDA for chronic pain treatment. The FDA focuses on market entry for prescription drugs rather than regulating clinicians prescribing practices, thus allowing off-label use of medications for indications beyond those formally evaluated by the manufacturer. Clinicians are to use their best knowledge and judgment, with the inherent responsibility to be well informed and base their prescribing upon scientific rationale and sound medical evidence *[Reference]*.

    The basic elements to include anytime opioids are used are a diagnosis, a care plan, regular visits with the physician, follow-up, and documentation. See the Federation of State Medical Boards at: http://www.fsmb.org for complete information.

    General Principles for Pharmacologic Management *[Low Quality Evidence]*

    - A thorough medication history is critical to the development of an effective treatment plan.
        - Include use of over-the counter drugs and herbals and other supplements.
        - Look for drug-related fears and misconceptions, as they may lead to poor compliance with a therapeutic regimen. Differentiate between tolerance, physical dependence, and addiction. See "Definitions" in the original guideline document.
    - Define the goals of therapy before prescribing, and tailor medications to meet the individual goals of each patient.
    - Identify and treat specific source(s) of pain, and base the initial choice of medication(s) on the severity and type of pain.
        - Types include neuropathic, muscular, inflammatory, and mechanical/compressive pain. See Annotations #15-18 above.
        - Give drugs an adequate therapeutic trial. When treating inflammatory or neuropathic pain, benefits may take weeks or longer

to appear.

- Patients need to know that whether prescribed or non-prescribed, all drugs have risks and benefits. Watch for and manage side effects.
- Select an appropriate drug based on:
  - Characteristics of the agent (onset, duration, available routes of administration, dosing intervals, side effects). The least invasive route of administration is preferred; it's generally oral.
  - Patient factors (age, co-existing diseases, other medications, and response to previous treatments).
- Establish a pain management plan that may include the addition of other drugs: non-opioid, plus opioid, plus adjuvant analgesics when indicated.
  - Rational poly-pharmacy may include the use of two or more drugs with complementary mechanisms of action that may provide greater pain relief with less toxicity and lower doses of each drug.
  - Avoid prescribing two drugs in the same class at the same time.
  - Be alert for possible interactions with other medication the patient is taking or additive side effects.
- Titrate doses to achieve optimal balance between analgesic benefit, side effects, and functional improvement.
  - Some medications require gradual upward titration to achieve optimal analgesia and to minimize adverse effects.
  - Optimize administration of analgesics. Generally, better pain control is obtained with regularly scheduled doses and supplemented with as-needed doses for breakthrough pain.
- Taper and discontinue drugs that don't meet treatment goals. If a drug does not produce the desired therapeutic outcome, there is no need to continue it. This practice helps to prevent expensive and potentially dangerous poly-pharmacy.

Non-Opioid Analgesics

Non-opioid analgesics to consider for use in the treatment of chronic pain include acetaminophen and NSAIDs.

Acetaminophen is an analgesic that may be used initially for the treatment of mild chronic pain or to supplement other agents in treating mild to moderate pain. It lacks anti-inflammatory effects, but is generally well tolerated at therapeutic doses. It does not damage the gastric mucosa but may have chronic renal or hepatic adverse effects *[Low Quality Evidence]*. Dosage should be restricted to a maximum of 3 grams per 24 hours, including acetaminophen contained in combination opioid products such as hydrocodone with acetaminophen. Acetaminophen should be used cautiously or avoided in patients with liver impairment.

NSAIDs

NSAIDs are indicated for the treatment of mild to moderate inflammatory or non-neuropathic pain. In general, NSAIDs should be used for periodic flair-ups rather than for long-term chronic use. All NSAIDs inhibit the enzyme cyclooxygenase (COX), inhibiting prostaglandin synthesis. The COX-2 inhibitor celecoxib appears to have fewer gastrointestinal (GI) side effects.

However, high dose, long-term use of COX-2 agents has a higher rate of cardiovascular adverse effects. Recent reports indicate that cardiovascular adverse effects are not limited to the COX-2 agents alone *[Not Assignable]*.

- All NSAIDs have GI risks of gastritis and possible bleeding. Risk benefits should be weighed especially when treating elderly patients or those at higher risk for GI adverse effects. Consider using in combination with the gastroprotective agent misoprostol or a proton pump inhibitor.
- Use with caution in patients with coagulopathies or thrombocytopenia and those at risk for bleeding. At recommended doses, celecoxib does not appear to affect platelet counts, prothrombin time, partial thromboplastin time, or platelet aggregation. Celecoxib, at doses 2 to 4 times the maximum doses for rheumatoid arthritis (RA) and osteoarthritis (OA) (400 mg twice a day), respectively, was associated with a decreased incidence of anemia when compared with patients receiving NSAIDs (diclofenac and ibuprofen) at accepted RA and OA doses (2% versus 4.4%, respectively; p value less than or equal to 0.05) *[High Quality Evidence]*.
- Ketorolac should not be used for longer than five days and therefore is not an appropriate choice of NSAID in the treatment of chronic pain.
- NSAIDs have significant opioid dose-sparing properties and in turn may reduce opioid-related side effects.
- Monitor all NSAID use including patient use of non-prescription drugs to prevent duplication of therapy and adverse effects.

Choosing Wisely®

The use of NSAIDs should be avoided in individuals with hypertension, heart failure, or chronic kidney disease (CKD) of all causes, including diabetes for musculoskeletal pain due to increased renal insufficiency.*

*This is in alignment with the recommendations made by the American Society of Nephrology as part of the Choosing Wisely® campaign, and additional information can be found at http://www.asn-online.org/choosingwisely .

Opioids

When Is It Appropriate to Use Opioids?

Prior to consideration of opioid use for the patient with chronic pain, a thorough evaluation as recommended in the guideline document should have been completed. If the ethical imperative to relieve pain requires opioid therapy prior to such a thorough evaluation, precede using good clinical judgment.

It is appropriate to consider opioid therapy for patients with persistent moderate to severe pain in the following circumstances:

- Clinical evidence suggests opioids are likely to be effective in neuropathic pain that is not responsive to initial therapies (TCAs or gabapentin).
- Opioids are rarely beneficial in the treatment of inflammatory or mechanical/compressive pain and are not indicated for chronic use in treatment of headache (see the NGC summary of the ICSI guideline Diagnosis and treatment of headache).
- Opioids have an equal or better therapeutic index than alternative therapies.
- The medical risk of opioid therapy is relatively low.
- The patient is likely to be responsible in using the drug.
- Opioid therapy is considered part of the overall management for the pain syndrome.

The Four A's

The goal of opioid therapy is to provide partial analgesia, and maintain or improve function with acceptable side effects. (Four A's: Analgesia, Adverse drug effects, Activity, Adherence) *[Guideline]*.

At each patient visit, the assessment should specifically address these goals (with clear documentation of the 4 A's in the patient's medical record):

- Comfort (degree of analgesia)
- Opioid-related side effects
- Functional status (physical and psychosocial)
- Existence of aberrant drug-related behaviors

Opioid Management

Opioids have the potential to alleviate pain but also the potential for aberrant drug-related behavior, drug abuse, or misuse. Therefore, a single physician/clinician should prescribe and supervise opioids used for chronic non-cancer pain. Often the primary care provider is best suited to do so based on knowledge of the whole person *[Guideline]*. Physicians should not feel compelled to prescribe opioids or any drug if it is against their honest judgment or if they feel uncomfortable prescribing the drug. Additionally, those who prescribe opioid pain medication should be aware of current federal and state laws and regulations related to the use of chronic opioid therapy *[Guideline]*.

Before prescribing an opioid and other potentially addictive medications, or medications of potential abuse or misuse, the work group recommends completion of a comprehensive biopsychosocial assessment. This should include pain history/examination plus administration of an opioid assessment tool to recognize potential risks of addiction, abuse or misuse. Prior medical records, particularly pertaining to pain medications, should be reviewed before deciding to start chronic opioid pain medications.

Diagnosis, Intractability, Risk, Efficacy (DIRE) Tool

Opioid assessment tools, such as the DIRE tool, determine a patient's appropriateness for long-term opioid management (see Appendix E, "DIRE Score: Patient Selection for Chronic Opioid Analgesia," in the original guideline document). In a reliability and validity study, higher scores (14 or higher) predicted a more successful prescribing process with respect to patient compliance and efficacy of treatment *[High Quality Evidence]*.

Screening, Brief Intervention, Referral to Treatment (SBIRT) Model for Substance Use

For those patients who have a positive screen for misuse of drugs or alcohol, SBIRT is a comprehensive and integrated approach to the delivery of early intervention and treatment services. SBIRT reduces alcohol consumption and alcohol-related harm when done in the outpatient or emergency department settings.

Additional information can be obtained at ICSI SBIRT Model and Implementation.

Other opioid assessment tools include:

- Webster's Opioid Risk Tool (ORT)
- Screener and Opioid Assessment for Patients in Pain (SOAPP®)
- Current Opioid Misuse Measure (COMM™)
- Prescription Drug Use Questionnaire (PDUQ)
- Screening Tool for Addiction Risk (STAR)
- Screening Instrument for Substance Abuse Potential (SISAP)
- Pain Medicine Questionnaire (PMQ)

Patients should give informed consent before the start of opioid therapy and the consent discussion should be documented in the medical record. This discussion should include the necessity of adherence to prescribed dosing, the potential for cognitive impairment when taking the drug alone and/or in combination with sedative/hypnotics, and the likelihood that physical dependence will occur *[Guideline]*. Chronic use of opioids has many other potential hazards. These hazards include the potential for addiction, tolerance, hyperalgesia and hyperkatifeia. Rates of overdose and associated deaths are increasing. This is in the context that chronic use of opioids may be effective in pain control in only 30% *[Systematic Review]* of those with chronic pain. Aberrant use of opioids is common occurring in up to 24% of this population *[Systematic Review]*. In general, use of opioids may delay recovery *[Low Quality Evidence]* from chronic pain and have not been shown to increase function. They may decrease sexual and immune function as well as increase overall mortality rate *[Reference]*.

Refer to the original guideline document for information about general principles of opioid management.

Substance Abuse

Patients should be carefully screened for risk of diversion or abuse. The following behaviors suggest relative contraindications to opioid use. With these patients, referral to pain or addiction specialist is advisable *[Guideline]*:

- History of substance abuse or prior prescription drug misuse
- Unsanctioned dose escalations on several occasions
- Non-adherence to other recommendations for pain therapy
- Unwillingness or inability to comply with treatment plan
- Social instability
- Unwillingness to adjust at-risk activities resulting in serious re-injury requiring additional opioid prescriptions

Random drug screens are one tool to monitor compliance with the opioid regimen. Random urine drug screens are used: (1) to check for diversion, seeking evidence the patient is taking the medication being prescribed; (2) to check for drugs of abuse; and (3) to test for the presence of the prescribed drug. Any evidence of street drug use indicates non-compliance with the opioid contract. The patient's opioids are tapered and he or she is referred to a chemical dependence specialist or treatment program. Primary care physicians need to be aware of the limits of a drug screen. Other useful tools include periodic pill counts or consultation with an addiction medicine specialist, or use of a centralized database to identify and monitor usage (http://www.pmp.pharmacy.state.mn.us/).

Evidence of aberrant drug-related behaviors must be carefully assessed. In some cases tapering and discontinuation of opioid therapy will be necessary. Other patients may appropriately continue therapy if the structure for monitoring is tightened. Consideration should be given to consultation with an addiction medicine specialist.

There is not enough evidence to permit generalizable conclusions regarding the abuse of opioids in chronic nonmalignant pain. However, careful patient selection and close monitoring of all nonmalignant pain patients on chronic opioids is necessary to assess effectiveness and watch for signs of abuse.

When there is non-compliance, escalation of opioid use, or increasing pain not responding to increasing opioids, consider whether this represents a response to inadequate pain control (pseudoaddiction, tolerance or opioid-induced hyperalgesia) or a behavioral problem indicating the patient is not a candidate for opioid therapy *[Systematic Review]*, *[Low Quality Evidence]*.

Refer to the original guideline document for information on the following topics:

- Opioid-independent pain
- Opioid-induced hyperalgesia
- Opioids and function
- Considerations for initiating and discontinuing opioid therapy
- Clearance and metabolism of opioids
- Specific opioid characteristics

See also Appendix G in the original guideline document for additional information on opioids.

TCAs

TCAs have a role in the treatment of neuropathic pain, especially if the patient has co-existing insomnia, anxiety, or depression *[Systematic Review]*, *[Low Quality Evidence]*. TCAs are categorized as secondary amines (nortriptyline or desipramine) or tertiary amines (amitriptyline and imipramine). Both classes are effective in the treatment of neuropathic pain but the tertiary amines have more anticholinergic side effects and generally should be avoided in the elderly.

- Analgesic effects of TCAs are independent of their antidepressant effect, and analgesia may be seen with lower doses.
- Start low and increase doses gradually over several weeks to months. Maximum analgesic effect may take several weeks or longer to be seen.
- Baseline electrocardiogram (ECG) is indicated in patients at risk for cardiac adverse effects.
- Common side effects include sedation, dry mouth, constipation, and urinary retention. Use caution in patients with conditions that may be aggravated by TCAs, including heart disease, symptomatic prostatic hypertrophy, neurogenic bladder, dementia, and narrow-angle glaucoma.

Other Antidepressants -- Selective Serotonin Reuptake Inhibitors (SSRIs) and Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs)

Tricyclic drugs are often used first line for fibromyalgia, but other antidepressants could be used concurrently or to replace tricyclics in patients who do not have adequate response or cannot tolerate side effects.

The selective serotonin reuptake inhibitor class of antidepressants has reduced adverse effects compared with TCAs, but efficacy in the treatment of neuropathic pain is generally not as good as that shown with TCAs. Bupropion *[Moderate Quality Evidence]*, venlafaxine *[Low Quality Evidence]*, and duloxetine *[High Quality Evidence]* have also shown efficacy in the treatment of neuropathic pain. Duloxetine has been shown to improve pain and global measures of fibromyalgia, compared with placebo *[High Quality Evidence]*. Duloxetine dosed 60 mg twice daily is indicated in the treatment of fibromyalgia.

Dual reuptake inhibitors increase norepinephrine and serotonin without producing the cardiac adverse effects associated with the tricyclics. In addition to duloxetine, milnacipran is indicated in the treatment of fibromyalgia. Milnacipran is initiated at a dose of 12.5 mg once daily and titrated over seven days to a target dose of 50 to 100 mg two times per day.

Anticonvulsant or Antiepileptic Drugs

The first generation anticonvulsants carbamazepine and phenytoin are effective in the treatment of neuropathic pain but may have unwanted central nervous system (CNS) side effects. Carbamazepine is approved for the treatment of trigeminal neuralgia and benefits are well established *[Systematic Review]*.

Pregabalin is indicated for treatment of diabetic neuropathy, postherpetic neuralgia, and fibromyalgia.

Oxcarbazepine is chemically similar to carbamazepine and may have benefits in the treatment of neuropathic pain, including trigeminal neuralgia and diabetic neuropathy.

The second generation agent gabapentin is approved for the treatment of postherpetic neuralgia, but has been shown to have analgesic effects in many cases of neuropathic pain syndromes *[Moderate Quality Evidence]*, *[High Quality Evidence]*. To decrease the incidence of adverse effects, which are primarily somnolence and dizziness, start at low doses and titrate up gradually.

Lamotrigine has efficacy in trigeminal neuralgia, neuropathies associated with human immunodeficiency virus infection, and post-stroke pain.

Topical Agents

Topical NSAIDs can provide acceptable levels of pain relief in knee and hand osteoarthritis, and are available through a diclofenac 0.3% topical patch and 1% topical gel. Topical formulations provide more localized pain relief with efficacy comparable to oral products. They generally have a lower incidence of GI adverse effects compared with oral NSAIDs. Topical NSAID GI adverse effects did not differ from placebo but were less frequent than with oral NSAIDs *[Systematic Review]*.

Topical lidocaine 5% patches are FDA approved for postherpetic neuralgia and have shown efficacy in other neuropathic pain syndromes. Systemic absorption of lidocaine is minimal and the patch has a clean safety profile with the correct dosage schedule.

Capsaicin, the active ingredient in the herbal product cayenne, is used topically to deplete the pain mediator substance-P from afferent nociceptive neurons. Topical creams and solutions have been used in treating both neuropathic pain and arthritic pain. Capsaicin should be applied for at least six weeks to see full benefits. The side effect of local burning is common, and most patients become tolerant after a few days *[Systematic Review]*, *[High Quality Evidence]*, *[Low Quality Evidence]*.

Refer to the original guideline document for information on muscle relaxants and antispasmodics, anxiolytics, and drugs for insomnia.

Intervention Management

Recommendations:

- Therapeutic procedures are used to alleviate or reduce chronic pain and should be used in conjunction with a comprehensive treatment plan developed by a chronic pain specialist.
- Interventional techniques should be performed in conjunction with a comprehensive treatment plan that includes pharmacologic, rehabilitative, and psychological interventions.
- Many of the Level I procedures provide both diagnostic and therapeutic benefits, while Level II are reserved for patients who have failed conventional treatment.
- Diagnostic procedures are used to identify neural or musculoskeletal structures that are the source of the patient's pain symptoms.
- The role of intervention modalities is different for chronic pain than acute and should be carefully evaluated by a pain specialist.

Interventional techniques refer to procedures including spinal injections, nerve blocks, spinal cord stimulators, and implantable intrathecal drug delivery systems that are performed in an attempt to diagnose and treat chronic pain. If used alone, the evidence is limited in its success. These procedures should be performed in conjunction with a comprehensive treatment plan that includes pharmacologic, rehabilitative, and psychological interventions. Commonly performed interventional procedures will be categorized as Level I (diagnostic and therapeutic) and Level II (palliative). Many of the Level I procedures provide both diagnostic and therapeutic benefits while Level II interventions are reserved for patients who have failed conventional treatment.

The role of intervention modalities is different for chronic pain than acute and should be carefully evaluated by a pain specialist.

See also Annotation #25, "Level II Management: Interdisciplinary Team Referral, Plus a Pain Medicine Specialist or Pain Medicine Specialty Clinic," below.

Level I Diagnostic Procedures

Examples of commonly performed Level I diagnostic procedures include sacroiliac joint injection, transforaminal epidural injection, and discography.

Level I Therapeutic Procedures

Examples of commonly used Level I therapeutic procedures include facet joint injection, percutaneous radiofrequency neurotomy, epidural corticosteroid injections, transforaminal epidural injection, and sacroiliac joint injection.

Refer to the original guideline document for detailed information on Level I diagnostic and therapeutic procedures.

Complementary Management

Acupuncture

Clinical research with randomized, placebo-controlled trials supports the use of acupuncture for certain chronic pain conditions such as fibromyalgia *[High Quality Evidence]*, *[Low Quality Evidence]*, headache *[Low Quality Evidence]*, back pain *[Low Quality Evidence]*, neck pain *[Low Quality Evidence]*, and osteoarthritis of the knee *[Low Quality Evidence]*.

Refer to the original guideline document for more information on acupuncture.

Herbal Products Used for Pain

While there are many herbal products used for pain, the following have some supporting data for use in the treatment of pain, but may still have significant potential for drug interactions and adverse effects: devil's claw, dimethylsulfoxide (DMSO), feverfew, glucosamine and chondroitin, and willow bark. DMSO is mentioned due to the frequency of use, despite evidence of toxicity and lack of documented efficacy.

Refer to the original guideline document for more detailed information on herbal products and healing touch used for pain.

24. Has Enough Been Tried with Level I Management?
Failing to achieve improvement in chronic pain management using Level I management strategies, the primary care physician should consider a consultation and/or referral to a pain medicine specialist or pain medicine specialty clinic.

Reasons for consultation may include:

- Diagnostic assistance
- Advice on availability of current care plan and treatment strategies
- Advice on optimal pharmacotherapy
- Help with treatment planning for long-term pain management

Referral to a comprehensive pain management program may be considered as early as four to eight weeks after the onset of acute pain and should be strongly considered when a patient needs an intensive comprehensive evaluation by a pain management team (physician, psychologist, physical therapist, pharmacist, etc.). The team should have extensive training and experience in pain management and each professional should be working as part of an interdisciplinary team to meet the patient's needs.

The team works as part of a structured integrated long-term program where the goal is effective stabilization of the patient's pain, development of a pain management care plan, and return of the patient to be a functioning member of society.

25. Level II Management: Interdisciplinary Team Referral, Plus a Pain Medicine Specialist or Pain Medicine Specialty Clinic Recommendation:

    - The Level II interdisciplinary team should do a thorough biopsychosocial assessment of the patient with chronic pain, and a comprehensive plan of care should be developed with active input from the patient and primary care clinician.

    Level II management of patients with chronic pain is indicated when the patient has had a thorough trial of Level I management (see annotations #14-24 above), yet has not met the goals of comfort/pain control and function. Level II management should include an interdisciplinary team including the primary care clinician, a medical pain specialist, a behavioral health pain specialist, and a physical therapist trained in a biopsychosocial approach to chronic pain. If possible, this management should be provided in the patient's community. If an interdisciplinary Level II pain team is not available in the community, it may be necessary to obtain these services outside the community. As with Level I management, Level II management should continue to be coordinated by the primary care clinician.

    Level II interdisciplinary chronic pain team assessment should be obtained in a timely manner, sometimes as early as four to eight weeks after the onset of acute pain. The goal is to prevent or effectively manage chronic pain syndrome (disability in work or personal function related to pain).

    The Level II interdisciplinary team should do a thorough biopsychosocial assessment of the patient with chronic pain. A comprehensive plan of care should be developed with active input from the patient and primary care clinician. The plan of care should focus on objective functional goals and pain management. Elective surgery and invasive procedures should be done after the Level II interdisciplinary team assessment. Specific goals to integrate the patient back into the community and to usual activities should be a part of the plan of care.

Definitions:

Following a review of several evidence rating and recommendation writing systems, Institute for Clinical System Improvement (ICSI) has made a decision to transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.

Crosswalk between ICSI Evidence Grading System and GRADE

ICSI GRADE System	**Previous ICSI System**	
High, if no limitation	**Class A:**	Randomized, controlled trial
Low	**Class B:**	[observational]
		Cohort study
	Class C:	[observational]
		Non-randomized trial with concurrent or historical controls
Low		Case-control study
Low		Population-based descriptive study

ICSI GRADE System	Previous ICSI System	
*Low		Study of sensitivity and specificity of a diagnostic test
*Following individual study review, may be elevated to Moderate or High depending upon study design		
	Class D:	[observational]
Low		Cross-sectional study
		Case series
		Case report
Meta-analysis	**Class M:**	Meta-analysis
Systematic Review		Systematic review
Decision Analysis		Decision analysis
Cost-Effectiveness Analysis		Cost-effectiveness analysis
Low	**Class R:**	Consensus statement
Low		Consensus report
Low		Narrative review
Guideline	**Class R:**	Guideline
Low	**Class X:**	Medical opinion

Evidence Definitions

High Quality Evidence = Further research is very unlikely to change confidence in the estimate of effect.

Moderate Quality Evidence = Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.

Low Quality Evidence = Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain.

In addition to evidence that is graded and used to formulate recommendations, additional pieces of literature will be used to inform the reader of other topics of interest. This literature is not given an evidence grade and is instead identified as a Reference throughout the document.

Clinical Algorithm(s)

The following algorithms are provided in the original guideline document :

- Assessment algorithm
- Management algorithm

Scope

Disease/Condition(s)

Chronic pain, including neuropathic pain, muscle pain, inflammatory pain, and mechanical/compressive pain

Note: The work group has defined chronic pain as "pain without biological value that has persisted beyond the normal time and despite the usual customary efforts to diagnose and

treat the original condition and injury."

Other Disease/Condition(s) Addressed

- Depression
- Substance-related disorders

Guideline Category

Evaluation

Management

Rehabilitation

Treatment

Clinical Specialty

Anesthesiology

Family Practice

Internal Medicine

Neurology

Physical Medicine and Rehabilitation

Psychology

Surgery

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Health Plans

Hospitals

Managed Care Organizations

Nurses

Occupational Therapists

Patients

Pharmacists

Physical Therapists

Physician Assistants

Physicians

Psychologists/Non-physician Behavioral Health Clinicians

Guideline Objective(s)

- To improve the function of patients age 18 years and older with chronic pain
- To improve the assessment and reassessment of patients age 18 years and older with chronic pain diagnosis utilizing the biopsychosocial model
- To improve the appropriate use of Level I and Level II treatment approaches for patients age 18 years and older with chronic pain
- To improve the effective use of non-opioid medications in the treatment of patients age 18 years and older with chronic pain
- To improve the effective use of opioid medications in the treatment of patients age 18 years and older with chronic pain

Target Population

Patients (18 years and older) with chronic pain

Note: This guideline can be applied to pediatric population where noted. This guideline is not intended for the treatment of migraine headaches, cancer pain, advanced cancer pain, or in the context of palliative care or end-of-life management.

Interventions and Practices Considered

Evaluation

1. Assessment
    - History and physical examination
    - Diagnostic testing (radiography, magnetic resonance imaging [MRI], computed tomography [CT])
2. Determining biological mechanism of pain
    - Neuropathic
    - Muscle
    - Inflammatory
    - Mechanical/compressive
3. Other assessments
    - Functional/quality of life
    - Psychological
4. Specialist consultation
5. Level I diagnostic procedures (e.g., sacroiliac joint injection, transforaminal epidural injection, discography)

Management/Rehabilitation/Treatment

1. Plan of care using biopsychosocial model
2. Exercise fitness program
3. Psychosocial management, including cognitive behavioral therapy
4. Shared decision-making and self-management
5. Physical rehabilitation
6. Level I management of neuropathic pain:
    - Tricyclic antidepressants (TCAs)
    - Cyclobenzaprine
    - Topical agents (lidocaine, capsaicin)
    - Anticonvulsants
    - Opioids
7. Level I management of muscle pain:
    - Physical rehabilitation
    - Behavioral management
    - Drug therapy
8. Level I management of inflammatory pain:

    - Non-steroidal anti-inflammatory (NSAID) medications
    - Corticosteroids
9. Level I management of mechanical/compressive pain:
    - Surgical decompression or stabilization
    - Splinting
    - Strengthening
    - Use of assistive devices
    - Manipulative therapy
    - Opioids
10. Level I therapeutic procedures:
    - Facet joint injection
    - Percutaneous radiofrequency neurotomy
    - Epidural corticosteroid injections
    - Transforaminal epidural injection
    - Sacroiliac joint injection
11. Complementary management, including:
    - Acupuncture
    - Herbal products
    - Healing touch
12. Level II management
    - Interdisciplinary chronic pain team assessment
    - Comprehensive care plan

Major Outcomes Considered

- Effect of treatment on chronic pain
- Role of psychological factors in chronic pain
- Barriers to treatment of chronic pain

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

A consistent and defined process is used for literature search and review for the development and revision of Institute for Clinical Systems Improvement (ICSI) guidelines. The literature search was divided into two stages to identify systematic reviews (stage I) and randomized controlled trials, meta-analyses and other literature (stage II).

A literature search on the assessment and management of chronic pain was completed utilizing the PubMed and Cochrane databases, and the following search terms were included: opioids, gabapentin, non-steroidal anti-inflammatory drugs, capsaicin, and pain management in relation to chronic pain and published between August 2011 and August 2013. Non-human data and non-English language publications were excluded.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Rating Scheme for the Strength of the Evidence

Following a review of several evidence rating and recommendation writing systems, Institute for Clinical System Improvement (ICSI) has made a decision to transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.

Crosswalk between ICSI Evidence Grading System and GRADE

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*Following individual study review, may be elevated to Moderate or High depending upon study design		
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		Case series
		Case report
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Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

New Guideline Development Process

A work group consisting of 6 to 12 members that includes physicians, nurses, pharmacists, other healthcare professionals relevant to the topic, and an Institute for Clinical Systems Improvement (ICSI) staff facilitator develops each document. Ordinarily, one of the physicians will be the leader. Most work group members are recruited from ICSI member organizations, but if there is expertise not represented by ICSI members, 1 or 2 work group members may be recruited from medical groups, hospitals or other organizations that are not members of ICSI. Patients on occasion are invited to serve on work groups.

The work group will meet for 7 to 8 three-hour meetings to develop the guideline. A literature search and review is performed and the work group members, under the coordination of the ICSI staff facilitator, develop the algorithm and write the annotations and literature citations.

Once the final draft copy of the guideline is developed, the guideline goes to the ICSI members for critical review.

Revision Process of Existing Guidelines

ICSI scientific documents are revised every 12 to 24 months as indicated by changes in clinical practice and literature. For documents that are revised on a 24-month schedule, ICSI checks with the work group on an annual basis to determine if there have been changes in the literature significant enough to cause the document to be revised earlier or later than scheduled. For yearly reviewed documents, ICSI checks with every work group 6 months before the scheduled revision to determine if there have been changes in the literature significant enough to cause the document to be revised earlier than scheduled.

Literature Search

ICSI staff, working with the work group to identify any new pertinent clinical trials, systematic reviews, or regulatory statements and other professional guidelines, conduct a literature search.

Revision

The work group will meet for 1 to 2 three-hour meetings to review the literature, respond to member organization comments, and revise the document as appropriate.

A second review by members is indicated if there are changes or additions to the document that would be unfamiliar or unacceptable to member organizations. If a review by members is not needed, the document goes to the appropriate steering committee for approval according to the criteria outlined in the "Description of Method of Guideline Validation" field.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Critical Review Process

The purpose of Critical Review is to provide an opportunity for the clinicians in the member groups to review the science behind the recommendations and focus on the content of the guideline. Critical review also provides an opportunity for clinicians in each group to come to consensus on feedback they wish to give the work group and to consider changes needed across systems in their organization to implement the guideline.

All member organizations are expected to respond to critical review guidelines. Critical review of guidelines is a criterion for continued membership within the Institute for Clinical Systems Improvement (ICSI).

After the critical review period, the guideline work group reconvenes to review the comments and make changes as appropriate. The work group prepares a written response to all comments.

Document Approval

Each document is approved by the Committee for Evidence-Based Practice (CEBP).

The committee will review and approve each guideline/protocol, based on the following criteria:

- The aim(s) of the document is clearly and specifically described.
- The need for and importance of the document is clearly stated.
- The work group included individuals from all relevant professional groups and had the needed expertise.
- Patient views and preferences were sought and included.
- The work group has responded to all feedback and criticisms reasonably.
- Potential conflicts of interest were disclosed and do not detract from the quality of the document.
- Systematic methods were used to search for the evidence to assure completeness and currency.
- Health benefits, side effects, risks and patient preferences have been considered in formulating recommendations.
- The link between the recommendation and supporting evidence is clear.
- Where the evidence has not been well established, recommendations based on community practice or expert opinion are clearly identified.
- Recommendations are specific and unambiguous.
- Different options for clinical management are clearly presented.
- Clinical highlights and recommendations are easily identifiable.
- Implementation recommendations identify key strategies for *health care systems* to support implementation of the document.
- The document is supported with practical and useful tools to ease *clinician* implementation.
- Where local resource availability may vary, alternative recommendations are clear.
- Suggested measures are clear and useful for quality/process improvement efforts.

Once the document has been approved, it is posted on the ICSI Web site and released to members for use.

Evidence Supporting the Recommendations

References Supporting the Recommendations

Malmivaara A, Koes BW, Bouter LM, van Tulder MW. Applicability and clinical relevance of results in randomized controlled trials: the Cochrane review on exercise therapy for low back pain as an example. Spine (Phila Pa 1976). 2006 Jun 1;31(13):1405-9. PubMed

Passik SD, Weinreb HJ. Managing chronic nonmalignant pain: overcoming obstacles to the use of opioids. Adv Ther. 2000 Mar-Apr;17(2):70-83. PubMed

Type of Evidence Supporting the Recommendations

The type of supporting evidence is classified and/or graded for selected recommendations (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate assessment and management of chronic pain

Potential Harms

Adverse Effects of Medications

Acetaminophen

Acetaminophen does not damage the gastric mucosa but may have chronic renal or hepatic adverse effects. Dosage should be restricted to a maximum of 3 grams per 24 hours, including acetaminophen contained in combination opioid products such as hydrocodone with acetaminophen. Acetaminophen should be used cautiously or avoided in patients with liver impairment.

Non-steroidal Anti-inflammatory Drugs (NSAIDs)

- All NSAIDs have gastrointestinal (GI) risks of gastritis and possible bleeding. Risk benefits should be weighed, especially when treating elderly patients or those at higher risk for GI adverse effects. Consider using in combination with the gastroprotective agent misoprostol or a proton pump inhibitor.
- Cardiovascular side effects
- Use with caution in patients with coagulopathies or thrombocytopenia and those at risk for bleeding.

Selective Cyclooxygenase-2 (COX-2) Inhibitors

High-dose, long-term use of COX-2 agents has a higher rate of cardiovascular adverse effects than other NSAIDs.

Anticonvulsant Drugs or Antiepileptic Drugs

To decrease the incidence of adverse effects, which are primarily somnolence and dizziness, start at low doses and titrate up gradually.

Tricyclic Antidepressants (TCAs)

- Common side effects include sedation, dry mouth, constipation and urinary retention. Use caution in patients with conditions that may be aggravated by TCAs, including heart disease, symptomatic prostatic hypertrophy, neurogenic bladder, dementia and narrow-angle

glaucoma.
- Tertiary amines (amitriptyline, imipramine) have more anticholinergic side effects and generally should be avoided in the elderly patients.

Topical Capsaicin

The side effect of local burning is common, and most patients become tolerant after a few days.

Muscle Relaxants and Antispasmodics

Cyclobenzaprine has side effects similar to the TCAs, including drowsiness/dizziness, dry mouth and an increased risk for arrhythmias. Concurrent use of cyclobenzaprine with TCAs is not contraindicated, but patients should be monitored for the potential increase in these related adverse effects.

Tizanidine may cause hypotension.

Anxiolytics

Benzodiazepine side effects of sedation and respiratory depression may limit the amount of opioids that can be used safely. They also result in physical dependence when used long term.

Opioids

Chronic use of opioids has many potential hazards including the potential for addiction, tolerance, hyperalgesia and hyperkatifeia. Rates of overdose and associated deaths are increasing. Aberrant use of opioids is common, occurring in up to 24% of the population taking opioids. In general, use of opioids may delay recovery from chronic pain and they have not been shown to increase function. They may decrease sexual and immune function as well as increase overall mortality rate. Recent evidence has shown that opioids, in higher doses or over a prolonged period, can produce a state of hyperalgesia, i.e., amplified pain response. Hepatic and renal impairment can affect the metabolism of many opioids.

- *Morphine, Meperidine*: Morphine and meperidine are toxic in renal insufficiency (glomerular filtration rate [GFR] <60)
- *Methadone*: Due to the complexity of dosing and potential for cardiac adverse effects, the use of this opiate should be reserved for experienced practitioners. Methadone has been associated with QTc interval prolongation and other cardiac adverse effects including hypotension and other cardiac dysrhythmias. Patients should have a baseline electrocardiogram (ECG) prior to initiation of methadone, which is repeated after 30 days and then annually. More frequent ECG monitoring should be done when methadone doses exceed 100 mg per day.
- *Tramadol*: Serotonin syndrome, while rare, may occur when using serotonin-enhancing medications including anti-migraine, and anti-migraine and cyclobenzaprine.
- *Oxycodone*: A recent U.S. Food and Drug Administration (FDA) warning stated that the concomitant use of oxycodone hydrochloride controlled-release tablets with all CYP3A4 inhibitors such as macrolide antibiotics (e.g., erythromycin), azole-antifungal agents (e.g., ketoconazole) and protease inhibitors (e.g., ritonavir) may result in an increase in oxycodone plasma concentrations and may cause potentially fatal respiratory depression. Patients receiving oxycodone controlled-release tablets and a CYP3A4 inhibitors should be carefully monitored for an extended period of time, and dose adjustment should be made if warranted.
- *Codeine*: A recent FDA advisory has identified that infants of nursing mothers taking codeine may have an increased risk of morphine overdose if mother is an ultra-rapid metabolizer of codeine. When prescribing codeine to nursing mothers, physicians should choose their lowest dose for the shortest period of time and should closely monitor mother-infant pairs.
- *Fentanyl*: Death and life-threatening adverse events related to fentanyl overdose have occurred when the fentanyl patch was used to treat pain in opioid-naive patients and when opioid-tolerant patients have applied more patches than prescribed, changed the patch too frequently, and exposed the patch to a heat source. The FDA has received reports of serious side effects including death in patients who have taken the fentanyl buccal tablets.

Refer to Appendix G in the original guideline document for additional information on side effects of opioids used in chronic pain.

<u>Herbal Products</u>

- Patients who use herbal preparations should be cautioned about adverse effects, drug interactions and the potential impurities of these products.
- *Glucosamine* may affect blood glucose and should be avoided or used cautiously in diabetics.
- *Willow Bark*: Adverse effects are similar to aspirin therapy. Patients allergic to aspirin or NSAIDs may be allergic to willow bark.

<u>Acupuncture</u>

Common complications of acupuncture include fainting, discomfort and bruising. Infrequent complications include infection, pneumothorax, and nerve injury.

Transforaminal Epidural Injection

Cervical and some upper lumbar transforaminal epidural steroid injections have been associated with spinal cord and brain injuries resulting in permanent neurological deficits and/or death. These adverse events are most likely related to penetration of radicular arteries or the vertebral artery followed by administration of particulate corticosteroids, which results in embolization and severe vasospasm.

Transcutaneous Electrical Nerve Stimulation

Transcutaneous electrical nerve stimulation and other stimulation-based therapies may be irritating, particularly when allodynia is present.

Contraindications

Contraindications

- The use of NSAIDs for musculoskeletal pain should be avoided in individuals with hypertension, heart failure, or chronic kidney disease (CKD) of all causes, including diabetes due to increased renal insufficiency.
- Ketorolac should not be used for longer than five days and therefore is not an appropriate choice of NSAID in the treatment of chronic pain.
- Tapentadol should be avoided in patients with convulsive disorders and in those with severe renal or hepatic impairment.

Relative Contraindications to Opioid Use

With these patients, referral to pain or addiction specialist is advisable:

- History of substance abuse or prior prescription drug misuse
- Unsanctioned dose escalation on several occasions
- Nonadherence to other recommendations for pain therapy
- Unwillingness or inability to comply with treatment plan
- Social instability
- Unwillingness to adjust at-risk activities resulting in serious re-injury requiring additional opioid prescriptions

Qualifying Statements

Qualifying Statements

- The information contained in this Institute for Clinical Systems Improvement (ICSI) Health Care Guideline is intended primarily for health professionals and other expert audiences.
- This ICSI Health Care Guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients and families are urged to consult a health care professional regarding their own situation and any specific medical questions they may have. In addition, they should seek assistance from a health care professional in interpreting this ICSI Health Care Guideline and applying it in their individual case.
- This ICSI Health Care Guideline is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition.
- The off-label use of medications to treat chronic pain is a common practice, and due to the complexity of chronic pain and the minimal approval sought by drug manufacturers, many of the medications in this guideline have not undergone formal evaluation by the Food and Drug Administration (FDA) for chronic pain treatment. The FDA focuses on market entry for prescription drugs rather than regulating clinicians prescribing practices, thus allowing off-label use of medications for indications beyond those formally evaluated by the manufacturer. Clinicians are to use their best knowledge and judgment, with the inherent responsibility to be well informed and base their prescribing upon scientific rationale and sound medical evidence.

Implementation of the Guideline

Description of Implementation Strategy

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

Implementation Recommendation Highlights

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

- It is important to take both a clinical and an operational approach for successful implementation of this guideline.
- Develop a process that allows patients with chronic pain to see a dedicated care clinician who has an interest or expertise in chronic pain.
- Develop a process to work collaboratively with other care clinicians in prescribing opioids with shared patients (e.g., dentists, specialists).
- Establish a policy for monitoring and maintaining opioid agreements for prescription refills with other clinics, pharmacies, dentists and specialists.
- Develop a process for scheduling follow-up patient visits to deter drug-seeking behaviors with other care clinicians. For instance, support personnel calling patients to schedule follow-up appointments with dedicated chronic pain physician.
- Develop staff and physician training regarding the organization's process for treating patients with chronic pain that could include process of referrals to chronic pain provider within the system, follow-up visits, prescription refills and continuity of care.
- Coordinate a chronic pain care team that minimally consists of a physician champion and medical support staff. Suggestion for care clinicians from other disciplines includes pharmacy, chemical dependency, neurology, occupational medicine, anesthesiology/pain management, behavioral health, home care, social work, physical medicine and rehabilitation, and physical therapy.
- Determine population International Classification of Diseases, Ninth Revision (ICD-9)/ICD-Tenth Revision (ICD-10) codes for data collection that is unique to patients with chronic pain in your facility. Examples of this would be:
    - Low back pain
    - Headache
    - Neck pain
    - Fibromyalgia
    - Chronic pain
- Identify multidimensional pain assessment, functional assessment, psychological assessment, and opioid assessment tools that meet the needs of the care clinicians and are appropriate for the patient populations.
  Examples of pain assessment, functional assessment, and psychological assessment tools are, but not limited to:
    - Brief Pain Inventory (BPI)
    - Physical Functional Ability Questionnaire (FAQ5)
    - Oswestry Low Back Disability Index (refer to the National Guideline Clearinghouse [NGC] summary of the Institute for Clinical Systems Improvement [ICSI] guideline Adult acute and subacute low back pain)
    - Patient Health Questionnaire (PHQ-9)
    - Generalized Anxiety Disorder 7-item (GAD-7) scale

  Examples of opioid and substance abuse assessment tools are, but not limited to:
    - CAGE and CAGE-AID
    - Webster's Opioid Risk Tool (ORT)
    - Diagnosis, Intractability, Risk, Efficacy (DIRE) tool
    - Screener and Opioid Assessment for Patients in Pain (SOAPP®)

- Current Opioid Misuse Measure (COMM™)
- Prescription Drug Use Questionnaire (PDUQ)
- Screening Tool for Addiction Risk (STAR)
- Screening Instrument for Substance Abuse Potential (SISAP)
- Pain Medicine Questionnaire (PMQ)
- Alcohol Use Disorders Identification Test (AUDIT-C)
- Screening, Brief Intervention, Referral to Treatment (SBIRT)

Implementation Tools

Chart Documentation/Checklists/Forms

Clinical Algorithm

Quality Measures

Quick Reference Guides/Physician Guides

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Related NQMC Measures

Assessment and management of chronic pain: percentage of patients diagnosed with chronic pain with functional outcome goals documented in the medical record.

Assessment and management of chronic pain: percentage of patients diagnosed with chronic pain with referral to physical rehabilitation and/or behavioral management therapy.

Assessment and management of chronic pain: percentage of patients diagnosed with chronic pain with documentation of receiving education regarding their diagnosis of chronic pain, medications, importance of physical activity and/or any interventional procedures in the medical record.

Assessment and management of chronic pain: percentage of patients with chronic pain diagnosis with documentation of a pain assessment completed at initial visit using a standardized tool that addresses pain intensity, location, pattern, mechanism of pain, current functional status and follow-up plan.

Assessment and management of chronic pain: percentage of patients diagnosed with chronic pain with documentation of reassessment of pain at follow-up visits using a standardized tool that addresses pain intensity, location, pattern and current functional status.

Assessment and management of chronic pain: percentage of patients diagnosed with chronic pain with documentation of screening for major depression and chemical dependency.

Assessment and management of chronic pain: percentage of patients diagnosed with chronic pain who have documentation of a plan of care that addresses personal goals, sleep, physical activity, stress management and pain reduction in the medical record and identifies potential barriers to patient follow-up on plan of care.

Assessment and management of chronic pain: percentage of chronic pain patients who are referred to diagnostic and/or therapeutic procedures if the goals for pain control or functional status have not been met.

Assessment and management of chronic pain: percentage of patients diagnosed with chronic pain who have not met pain control or functional status goals who are referred to pain specialist or interdisciplinary pain team.

Assessment and management of chronic pain: percentage of patients diagnosed with chronic pain with a diagnosis of neuropathic pain who are prescribed a sedative analgesic OR anticonvulsant prior to use of opioids.

Assessment and management of chronic pain: percentage of patients diagnosed with chronic pain who are receiving opioids who have documentation of the four A's assessment: 1) the degree of analgesia, 2) current opioid-related side effects, 3) current functional status and 4)

existence of aberrant drug-related behaviors documented at each visit.

Assessment and management of chronic pain: percentage of patients diagnosed with chronic pain who are prescribed an opioid who have an opioid agreement form and urine toxicology screen documented in the medical record.

Assessment and management of chronic pain: percentage of patients diagnosed with chronic pain who are screened for chemical dependency before being prescribed opioid medication.

Assessment and management of chronic pain: percentage of patients diagnosed with chronic pain who are prescribed an opioid at a dose less than 100 mg per day of morphine.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Hooten WM, Timming R, Belgrade M, Gaul J, Goertz M, Haake B, Myers C, Noonan MP, Owens J, Saeger L, Schweim K, Shteyman G, Walker N. Assessment and management of chronic pain. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2013 Nov. 105 p. [168 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2005 Nov (revised 2013 Nov)

Guideline Developer(s)

Institute for Clinical Systems Improvement - Nonprofit Organization

Guideline Developer Comment

The Institute for Clinical Systems Improvement (ICSI) is comprised of 50+ medical group and hospital members representing 9,000 physicians in Minnesota and surrounding areas, and is sponsored by five nonprofit health plans. For a list of sponsors and participating organizations, see the ICSI Web site.

Source(s) of Funding

- The Institute for Clinical Systems Improvement (ICSI) provided the funding for this guideline. The annual dues of the member medical groups and sponsoring health plans fund ICSI's work. Individuals on the work group are not paid by ICSI, but are supported by their medical group for this work.
- ICSI facilitates and coordinates the guideline development and revision process. ICSI, member medical groups, and sponsoring health plans review and provide feedback, but do not have editorial control over the work group. All recommendations are based on the work group's independent evaluation of the evidence.

Guideline Committee

Committee on Evidence-Based Practice

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

The Institute for Clinical Systems Improvement (ICSI) has long had a policy of transparency in declaring potential conflicting and competing interests of all individuals who participate in the development, revision and approval of ICSI guidelines and protocols.

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Where there are work group members with identified potential conflicts, these are disclosed and discussed at the initial work group meeting. These members are expected to recuse themselves from related discussions or authorship of related recommendations, as directed by the Conflict of Interest committee or requested by the work group.

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Disclosure of Potential Conflicts of Interest

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Guideline Related Activities: Mayo Clinic Diabetic Neuropathy Pain guideline
Research Grants: Money paid directly to institution from Rummler Foundation
Financial/Non-Financial Conflicts of Interest: Money paid previously by Purdue Pharma directly to work group member

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Guideline Related Activities: None
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Financial/Non-Financial Conflicts of Interest: None

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Research Grants: Rummler Hope Foundation money paid to institution for opioid addiction awareness
Financial/Non-Financial Conflicts of Interest: Purdue Pharma money paid to work group member and institution

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Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

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Guideline Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Guideline Status

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

Guideline Availability

The updated guideline is available from the Institute for Clinical Systems Improvement (ICSI) Web site .

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; Web site: www.icsi.org ; e-mail: icsi.info@icsi.org.

Availability of Companion Documents

The following is available:

- Assessment and management of chronic pain. Executive summary. Bloomington (MN): Institute for Clinical Systems Improvement; 2013 Nov. 1 p. Electronic copies: Available in Portable Document Format (PDF) from the Institute for Clinical Systems Improvement (ICSI) Web site .

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org ; e-mail: icsi.info@icsi.org.

Additionally, the following forms are available in the appendices of the original guideline document :

- Brief Pain Inventory (BPI)
- Patient Health Questionnaire (PHQ-9)
- Physical Functional Ability Questionnaire (FAQ5)
- Personal Care Plan for Chronic Pain
- DIRE Score: Patient Selection for Chronic Opioid Analgesia
- Opioid Agreement Form
- Neuropathic Pain Treatment Diagram

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI on January 13, 2006. This summary was updated by ECRI on November 16, 2006, following the

FDA advisory on Lamictal (lamotrigine). This summary was updated by ECRI on November 22, 2006, following the FDA advisory on Effexor (venlafaxine HCl). This NGC summary was updated by ECRI Institute on May 23, 2007. This summary was updated by ECRI Institute on November 9, 2007, following the U.S. Food and Drug Administration advisory on Antidepressant drugs. This summary was updated by ECRI Institute on January 10, 2008, following the U.S. Food and Drug Administration advisory on Carbamazepine. This NGC summary was updated by ECRI Institute on November 20, 2008. This summary was updated by ECRI Institute on March 10, 2009, following the U.S. Food and Drug Administration advisory on Topical Anesthetics. This summary was updated by ECRI Institute on May 1, 2009 following the U.S. Food and Drug Administration advisory on antiepileptic drugs. This summary was updated by ECRI Institute on July 20, 2009 following the U.S. Food and Drug Administration advisory on Darvon or Darvocet (Propoxyphene). This summary was updated by ECRI Institute on July 20, 2009 following the U.S. Food and Drug Administration advisory on Varenicline and Bupropion. This summary was updated by ECRI Institute on January 8, 2010 following the U.S. Food and Drug Administration advisory on Norpramin. This NGC summary was updated by ECRI Institute on June 17, 2010. This summary was updated by ECRI Institute on September 15, 2010 following the U.S. Food and Drug Administration advisory on Lamictal (lamotrigine). This summary was updated by ECRI Institute on March 16, 2011 following the U.S. Food and Drug Administration advisory on acetaminophen-containing prescription products. This summary was updated by ECRI Institute on June 5, 2012. This summary was updated by ECRI Institute on October 28, 2013 following the U.S. Food and Drug Administration advisory on Acetaminophen. This NGC summary was updated by ECRI Institute on February 21, 2014. This summary was updated by ECRI Institute on July 3, 2014 following the U.S. Food and Drug Administration advisory on Epidural Corticosteroid Injection. This summary was updated by ECRI Institute on September 18, 2015 following the U.S. Food and Drug Administration advisory on non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI Institute on June 2, 2016 following the U.S. Food and Drug Administration advisory on Opioid pain medicines. This summary was updated by ECRI Institute on October 21, 2016 following the U.S. Food and Drug Administration advisory on opioid pain and cough medicines combined with benzodiazepines. This summary was updated by ECRI Institute on February 15, 2017 following the U.S. Food and Drug Administration advisory on general anesthetic and sedation drugs.

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